# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 2026

## The Effect of 4% Topical Sucralfate in Erosive Candidial Diaper Dermatitis

## Protocol summary

**Study aim**
Determining the effect of 4% topical sucralfate in the treatment of erosive diaper dermatitis with candidiasis

**Design**
This study is a double-blind randomized clinical trial study (the patient and the examiner are blinded to the type of treatment) in which outpatients who visited the pediatric dermatology clinic of Imam Hossein (AS) Hospital in Isfahan between July 1401 and July 1402 or have been hospitalized in this center, they will be included in the study randomly in two groups. Written consent will be obtained from the parents of the children before entering the study and after explaining the study method.

**Settings and conduct**
The medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a completely covering thin layer on the skin. Necessary training will be given to the mother on how to use the medicine during the first visit. The place of study is Imam Hossein Children's Hospital, Isfahan.

**Participants/Inclusion and exclusion criteria**
Children less than two years and more than 30 days

**Intervention groups**
Intervention group: The medicine used is 4% sucralfate gel, the medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a thin layer covering the skin.

**Main outcome variables**
Diaper dermatitis severity percentage before, 3, 7 and 10 days after the intervention in case and control groups

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20221018056230N1**
Registration date: **2022-11-26, 1401/09/05**
Registration timing: **registered_while_recruiting**
Last update: **2022-11-26, 1401/09/05**
Update count: **0**

**Registration date**
2022-11-26, 1401/09/05

**Registrant information**

**Name**
Seyedh Zahra Moosavi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-11-22, 1401/09/01

**Expected recruitment end date**
2023-03-20, 1401/12/29

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The Effect of 4% Topical Sucralfate in Erosive Candidial Diaper Dermatitis

**Public title**
Investigation of 4% topical sucralfate in the topical treatment of children with diaper dermatitis

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Children less than 2 years after infancy with a new

clinical diagnosis of Candidiasis Rosacea due to diaper movement

**Exclusion criteria:**

**Age**

From **30 days** old to **2 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **32**

More than 1 sample in each individual

Number of samples in each individual: **4**

First, third, seventh, tenth days

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, No.1, Hezar jarib Blvd, Isfahan, Islamic Republic of Iran

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8174673461

**Approval date**

2022-07-31, 1401/05/09

**Ethics committee reference number**

IR.MUI.MED.REC.1401.179

## Health conditions studied

### 1

**Description of health condition studied**

Erosive Candidial Diaper Dermatitis

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Diaper dermatitis severity percentage before, 3, 7 and 10 days after the intervention in case and control groups

**Timepoint**

First, third, seventh and tenth days

**Method of measurement**

Diaper Severity Score

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: The medicine used is 4% sucralfate gel, the medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a thin layer covering the skin.The drug will be administered in the Faculty of Pharmacy of Isfahan University of Medical Sciences under the supervision of a pharmacist. To prepare one hundred grams of four percent sucralfate gel, first heat 85 ml of purified water on an electric heater until it reaches the boiling temperature, and after turning off the heat source at a temperature of 80 degrees Celsius, add 180 mg of methyl paraben and 20 A milligram of propyl paraben will be added to it, and then at a temperature of 50 degrees Celsius, one gram of carbomer 934, which has already been weighed, will be added to the formula.Half an hour later, that is, when the carbomer was hydrated, the formulation was stirred for 10 minutes with the help of a glass rod, and when the temperature of the formulation reached about 25 degrees Celsius, 4 grams of sucralfate powder, which was previously dissolved in ten milliliters of water, was added. The solution is added to the base and stirred with a glass rod for ten minutes until a homogeneous formulation is obtained. If the pH of the formulation is acidic, two drops of triethanolamine will be added and stirred to neutralize it. Finally, the final formulation will be packed in soft tubes. The contents on the tube box (consumer instructions) include the following: This medicine can only be used for skin use and under the supervision of a physician. In case of any skin reaction, consult the physician.The medicine should be stored at a temperature below 25 degrees Celsius and in a dry and cool place, away from direct sunlight and out of the reach of children. After opening the medicine tube, it can be used for up to one month at room temperature. Do not leave it in the environment and close it tightly. Avoid applying the medicine in sensitive areas such as around the eyes or on the face. Sample Size and Sampling Method: The sample size required for this study was calculated using the sample size

estimation formula to compare the averages mentioned below and considering the confidence level of 95%, the power of the test is 80%, the average number of times for Improvement of lesions in a similar study and taking into account the minimum significant difference between the two groups of case and control for 1 day, the number of samples required in each of the case and control groups was estimated to be 22 people, taking into account 10% sample loss. Eligible people to enter the study are randomly assigned to each of the case and control groups in a random permutation block method with a size of 4. How to use the medicine:The medicine will be applied every 4 or 5 hours when the child is awake, 5 times a day, in the affected area in the form of a completely covering thin layer on the skin. Necessary training will be given to the mother on how to use the medicine during the first visit. How to teach: The health and preventive measures that will be taught to mothers along with taking medicine are as follows: using linen diapers or washable cotton diapers that are washed and rinsed with soap, changing diapers or diapers regularly. As soon as the infant or child urinates, a complete explanation of the causes of diaper dermatitis including detergents, urine, diarrhea, the infant, the type of feeding and the type of diaper or the age of the infant. The number of training sessions: It is proportional to the visits of patients with their parents.Study grouping: In this study, patients are randomly divided into two groups with equal numbers. Both groups received standard treatment for diaper dermatitis including topical clotrimazole three times a day. In addition to being treated with clotrimazole ointment three times a day (every 8 hours), the treatment group is also treated with topical sucralfate 4% every 4 or 5 hours when the child wakes up 5 times a day.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Imam Hossein Hospital of Isfahan

**Full name of responsible person**
Parisa Iravani

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## Sponsors / Funding sources

### 1

**Sponsor**

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**Full name of responsible person**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Esfahan University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Seyedeh Zahra Moosavi

**Position**
Pediatric Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available